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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,149	08/15/2003	Allan J. Tobin	704611-3001	9827

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BINGHAM McCUTCHEN, LLP  
Three Embarcadero Center  
San Francisco, CA 94111-4067

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT PAPER NUMBER

1656

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/641,149

**Applicant(s)**

TOBIN ET AL.

**Examiner**

Gabriele E. BUGAISKY

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 39-42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/15/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/24/2003</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The Examiner has thus far been unable to obtain the parent application. Only the references which appeared on the face of the issued patent have been considered at this point. After 07/586536 has been reviewed, the Examiner will determine which of the cited references can be considered. A copy of the additional considered references will be supplied at that point. Please note that the citations for references 4-5 of sheet 2 are incomplete and only give a title and section information.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Specifically, Applicants are requested to ascertain that all sequences have a corresponding SEQ ID NO: and the specification be amended to incorporate these SEQ ID Nos.

Applicants are required under 37 C.F.R. 1.821-1.825 to amend their claims to specific sequences by citing the appropriate SEQ ID Nos.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleotides encoding at least the first hundred amino acids of the NH<sub>2</sub> terminus are recognized by GAD<sub>65</sub> autoantibodies., does not reasonably provide enablement for shorter DNA fragments encoding at least one epitope recognized by autoantibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims..

The disclosure reveals that autoantibodies from individual patients detect the GAD<sub>65</sub> protein encoded by the entire cDNA sequence of the instant invention, and that the greatest differences between GAD<sub>65</sub> and GAD<sub>67</sub> are in the 100 amino terminal amino acids. The disclosure does not reveal which specific portions of GAD<sub>65</sub> constitute epitopes that are recognized by autoantibodies, i.e., what features define a single epitope. An additional problem is that one does not *a priori* know that all sera with GAD<sub>65</sub> autoantibodies will recognize the identical epitopes on the protein. Thus, different batches of antisera could fail to detect an epitope recognized by a different batch of autoantibodies.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,

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8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention;

The claims are directed to DNA fragments encoding at least one epitope of human or rat GAD<sub>65</sub> that is recognized by autoantibodies

2) the breadth of the claims;

These claims are directed to a genus of any DNA fragment encoding at least one epitope that is recognized by autoantibodies. Thus, the claims extend from any 18-mer (since 6 amino acids are understood in the art to constitute an epitope) to longer polynucleotides

3) the predictability or unpredictability of the art;

The art is highly unpredictable. It is not clear that any random set of autoantisera will detect the same epitopes as other autoantisera,

4) the amount of direction or guidance presented;

As stated above, Applicants have revealed that autoantibodies from individual patients detect the GAD<sub>65</sub> protein encoded by the entire cDNA sequence of the instant invention, and that the greatest differences between GAD<sub>65</sub> and GAD<sub>67</sub> are in the 100 amino terminal amino acids. The disclosure does not reveal which specific portions of GAD<sub>65</sub> constitute epitopes that are recognized by autoantibodies, i.e., what features define a single epitope. An additional problem is that one does not *a priori* know that all sera with GAD<sub>65</sub> autoantibodies will recognize the identical epitopes on the protein. Thus, different batches of antisera could fail to detect an epitope recognized by a different batch of autoantibodies.

5) the presence or absence of working examples;

There is but a single working example, a full-length cDNA and the assertion that the greatest differences between GAD<sub>65</sub> and GAD<sub>67</sub> are in the 100 amino terminal amino acids.

6) the quantity of experimentation necessary;

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A great deal of experimentation would appear to be necessary to determine which subsequences encoding SEQ ID Nos 2 or 3 would produce peptides that possess epitopes that react with autoantibodies.

7) the state of the prior art;

The art provides minimal guidance on GAD<sub>65</sub>.

and 8) the relative skill of those skilled in the art;

In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a Ph.D. with several years of experience in the art. As the cited art would point to, even with a level of skill in the art which is high, predictability of the results is not invariable.

In consideration of each of factors 1 – 8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6682906. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to the patented claims and claim DNA encoding at least one epitope of Gad<sub>65</sub>. Claims 1-9 of the patent are directed to human GAD<sub>65</sub> nucleic acids and claims 10-18 are directed to rat Gad<sub>65</sub> nucleic acids. The instant claims recite both, in the alternative and encompass both the patented full-length cDNAs and those encoding the first 100 amino acids of the enzyme.

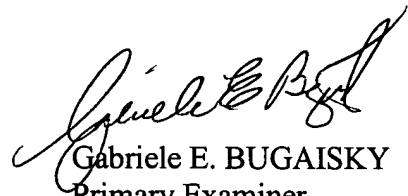
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1656